K121162

Attachment 5
510(K) Summary
Polaris Long Pulse and Q-Switched Ruby Laser

This 510(K) Summary of safety and effectiveness for Polaris Long Pulse and Q-Switched Ruby Laseris submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

JUL 18 2012

Applicant:	Sandstone Medical Technologies, LLC
Address:	105 Citation Court Birmingham, AL 35209
Contact Person:	Mark Rohrer
Telephone: Email:	205-290-8251 – phone ssmed@bellsouth.net
Preparation Date:	March 30, 2012
Device Trade Name:	Polaris Long Pulse and Q-Switched Ruby Laser
Common Name:	Long Pulse and Q-Switch Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	LaseAway Long Pulse and Q-Switched Ruby Laser (K)971193
Description of the Polaris Long Pulse and Q-Switched Ruby Laser	The Polaris Long Pulse and Q-Switched Ruby Laser and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. Energy is delivered using an articulated arm with interchangeable handpieces to adjust spot size. The wavelength is 694.3nm. The user activates laser by means of a footswitch.
Intended use:	The Polaris Long Pulse and Q-Switch Ruby Laser is intended to remove blue/black tattoos and benign dermal and epidermal pigmented lesions, and, to effect hair removal of patients with skin types 1-4 through selective targeting of melanin in hair follicles in dermatology and plastic surgery
Performance Data:	None
Results of Clinical Study:	None
Conclusion:	The Polaris Long Pulse and Q-Switched Ruby Laser is identical to the predicate device in terms of indications for use, technical specifications, operating performance features, general design.

Technical Specifications Comparison

	Polaris Long Pulse and Q-Switched Ruby Laser	LaseAway Q-Switch Ruby (Predicate Device)
Laser	Pulsed Ruby (Single lamp)	Pulsed Ruby (Single lamp)
Size	H840 mm x W495 mm x D680 mm	H840 mm x W495 mm x D680 mm
Weight	125Kg	125Kg
Power requirement	110V/220V 50/60 Hz (16A peak)	110V/220V 50/60 Hz (16A peak)
Cooling	Self contained refrigerated chiller	Self contained refrigerated chiller
Cooling medium	De-ionised water	De-ionised water
Wavelength	694.3nm	694.3nm
Aiming beam, HeNe	633nm	633nm
Repetition rate	1Hz	1Hz
Pulse duration, Q-Switched	25 ns	25 ns
Pulse duration, Long Pulse	2ms	2ms
Maximum energy Q-Switched	1.25 joules	1.25 joules
Maximum energy, Long Pulse	5 joules	5 joules
Spot size, Q-Switched	Selectable from 4, 5 and 6mm	Selectable from 4, 5 and 6mm
Spot Size, Long Pulse	Selectable from 5. 6 and 7mm	Selectable from 5. 6 and 7mm
Beam delivery	Articulated arm and focusing handpiece	Articulated arm and focusing handpiece
Ambient conditions	15° to 26°C, 10 to 80% humidity	15° to 26°C, 10 to 80% humidity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
105 Citation Court
Homewood, Alabama 35209

JUL 18 2012

Re: K121162
Trade/Device Name: Polaris Long Pulse and Q-Switched Ruby Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 30, 2012
Received: July 06, 2012

Dear Mr. Rohrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121162

Device Name: Polaris Long Pulse and Q-Switched Ruby Laser

The Polaris Long Pulse and Q-Switched Ruby Laser is intended to remove blue/black tattoos and benign dermal and epidermal pigmented lesions, and, to effect hair removal of patients with skin types 1-4 through selective targeting of melanin in hair follicles in dermatology and plastic surgery.

Prescription Use xx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121162